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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,241	08/21/2003	Lauren R. Ziegler	02-10	7532

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EXAMINER

MITCHELL, TEENA KAY

ART UNIT PAPER NUMBER

3743

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,241

Applicant(s)

ZIEGLER ET AL.

Examiner

Teena Mitchell

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 8-10, 12-14, 17, 18, 20 and 21 is/are rejected.
- 7) ☒ Claim(s) 3, 7, 11, 15, 16, 19 and 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 08/21/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 6 and 14 are objected to because of the following informalities:

"the second end of the holder..." lacks antecedent basis. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Klein (5,482,030).

Klein in a metered dose inhaler device discloses:

- a medication dispensing canister (24) and a canister holder (22),
the interactive character comprising:
- a base portion (16) adapted to be coupled to a canister (24) such
that activation of the canister to dispense a medication requires
providing an actuating force on the base portion (Note Fig. 3,
force applied at element 38);
- an interactive element (10) coupled to the base portion that
activates in a human perceivable manner (with respect to the
language of "a human perceivable manner" because the

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interactive element (10) moves counter disk (14) and a visual number is provided to the user, the interactive element meets the limitation of a human perceivable manner (i.e., the user is able to visually see the numerals as the device is activated and therefore a human perceivable manner); and

- an actuating means (via 38, 40, 42) responsive to the actuating force being applied to the base portion (16) to actuate the canister (24).

With respect to claim 2, Klein discloses wherein the interactive element (10) is a mechanical element that moves relative to the base portion, and wherein the actuating means (38, 40, 42) comprises linkage to the mechanical element (linkage via 50, 52, 56).

With respect to claim 8, Klein discloses wherein the actuating means comprises a pushrod (40) slideably mounted within the base portion (16), wherein the pushrod (40) includes a first end (38) adapted to engage the canister and a second end (50) adapted to engage a first portion of the interactive element (10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.**
- 2. Ascertaining the differences between the prior art and the claims at issue.**
- 3. Resolving the level of ordinary skill in the pertinent art.**
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.**

Claims 4, 5, 17, 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (5,482,030).

The difference between Klein and claim 4 is a light that changes from an deactivated condition to an activated state. Klein teaches that signaling devices of an audible, visual, or tactile are known in the prior art (Col. 9, lines 28-33). At the time the invention was made it would have been an obvious matter of design consideration to one of ordinary skill in the art to have a light as the interactive element because applicant has not disclosed that use of a light for the interactive element provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art would have expected applicant's invention to perform equally well with any visual device as such is known in the respiratory art as disclosed by Klein, and a visual aid is used to get the attention of a user of the device. Therefore, it would have been an obvious matter of design consideration to modify Klein to obtain the device of claim 4.

With respect to claim 5, note rejection of claim 4 above.

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With respect to claim 17, Klein discloses a base portion (16) and an interactive element (10) coupled to the base portion (with respect to the limitation of "in a human perceivable manner" because the interactive element of Klein has numerical means that a user can visually see, the limitation of in a human perceivable manner is met by Klein). The method steps would have been obvious because they would have resulted from the use of the device of Klein.

With respect to claim 18, Klein discloses a mechanical element relative to the base portion (10), a mechanical linkage (40) having a first end (38) coupled to the canister and a second end (50) operatively coupled to the mechanical element (10). The method steps would have been obvious because they would have resulted from the use of the device of Klein.

With respect to claims 20 and 21, note rejection of claim 4 above.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (5,482,030) in view of Puderbaugh et.al. (6,6026,807).

The difference between Klein and claim 6 is a spacer.

Puderbaugh in a metered dose inhaler teaches a spacer (100) providing a means to which permits more of the medication to reach those portions of the user's respiratory system where the medication is intended to be applied, and is more effective in respiratory care treatment (Col. 1, lines 35-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Klein to employ a spacer device doing so would have provided a means to which permits more of the medication to reach those portions of the user's respiratory system where the medication is

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intended to be applied, and is more effective in respiratory care treatment including the spacer taught by Puderbaugh.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rand et.al. (4,817,822).

With respect to claim 9, Rand in an aerosol medication delivery device discloses:

- a canister (102) having a first end (at area of 1) and a second end (at 2), wherein the canister (102) is adapted to dispense a medicine from the first end (at 4);
- a canister holder (101) adapted to be coupled to the canister, wherein the canister is moveable relative to the canister holder between a first position to a second position, and wherein a medicine is dispensed from the canister (102) responsive to the canister being the second position (the canister is moved vertically as the user pushes on the canister device at the second end and when the canister is in the second position (pushed down) the valve actuates (4) and delivery of medicament); and

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- an interactive character (22) comprising:
- a base portion (8) coupled to the second end of the canister (Figs. 1 and 2) such that movement of the canister to the second position is accomplished by applying an actuating force on the base portion (the user pushes on the base portion (8) which moves the canister downward to the second position),
- an interactive element (22) coupled to the base portion (8) that actuates in a human perceivable manner (because the interactive element has an indicating compartment which has a numerical means and provides the user with a visual indication of doses, such visual indicator constitutes a human perceivable manner), and actuating means (Col. 3, lines 53-68 and Col. 4, lines 1-35) for actuating the interactive element responsive to the actuating force being applied to the base portion (8; Col. 4, lines 35-45).

With respect to claim 10, Rand wherein the interactive element (22) is a mechanical element that moves relative to the base portion, and wherein the actuating means comprises a mechanical linkage coupled to the mechanical element (Col. 3, lines 45-68 and Col. 4, lines 1-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

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ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rand (4,817,822).

The difference between Rand and claim 12 is a light that changes from an deactivated condition to an activated state. It is well known in the respiratory art that visual aids are used in inhaler devices especially with young children. Therefore, at the time the invention was made it would have been an obvious matter of design consideration to one of ordinary skill in the art to have a light as the interactive element, because applicant has not disclosed that use of a light for the interactive element provides an advantage, is used for a particular purpose, or solves any stated problem. One of ordinary skill in the art would have expected applicant's invention to perform equally well with any visual device as such is known in the respiratory art as disclosed by Rand, and a visual aid is used to get the attention of a user of the device. Therefore, it would have been an obvious matter of design consideration to modify Rand to obtain the device of claim 12.

With respect to claim 13, note rejection of claim 12 above.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rand (4,817,822) in view of Puderbaugh et.al. (6,6026,807).

The difference between Rand and claim 14 is a spacer.

Puderbaugh in a metered dose inhaler teaches a spacer (100) providing a means to which permits more of the medication to reach those portions of the

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user's respiratory system where the medication is intended to be applied, and is more effective in respiratory care treatment (Col. 1, lines 35-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the inhaler of Rand to employ a spacer device doing so would have provided a means to which permits more of the medication to reach those portions of the user's respiratory system where the medication is intended to be applied, and is more effective in respiratory care treatment including the spacer taught by Puderbaugh.

Allowable Subject Matter

Claims 3, 7, 11, 15, 16, 19, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The overall combination of the interactive character with the limitations of a first and second anatomical feature, the base portion having a pair of grasping members disposed on the base portion and the limitations of claim 16 wherein the pushrod includes a first end adapted to engage the canister and a second end adapted to engage a first portion of the interactive element (with the limitations of claim 9) are neither anticipated nor rendered obvious by the prior art of record.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show metered dose inhaler

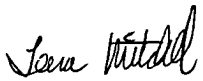
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devices and animated characters for containers: 6,708,688; 6,543,639;
6,267,639; 6,425,495; 5,799,651; 5,779,095; 5,456,626; 5,301,836; 5,172,863;
4,311,251; 2,117,370.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Teena Mitchell
Examiner
Art Unit 3743
June 27, 2004